

AMENDMENTS TO THE CLAIMS

1-9. (Canceled)

10. (Currently amended) A process for preparing ~~randomly ordered crystal agglomerates comprising an alkali metal clavulanate salt, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded, which comprises contacting a solution or suspension of alkali metal clavulanate salt in a solvent or mixture of solvents with one or more anti-solvents under stirring an agglomerate comprising potassium clavulanate, comprising;~~

a) contacting a potassium clavulanate crystal in a solvent or mixture of solvents to form a solution;

b) contacting said solution with an anti-solvent under stirring to cause precipitation of an agglomerate comprising potassium clavulanate,

wherein said agglomerate has a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form and is substantially free from non-agglomerate crystals in the needle form, and with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

11. (Canceled)

12. (Currently amended) A process according to claim 10, wherein the ratio of the weight of the solution containing the ~~clavulanate salt~~ potassium clavulanate to the anti-solvent is about 0.05 to 10 wt.%.

13. (Previously presented) A process according to claim 10, wherein the solvent is water, ethanol, or a mixture thereof, wherein water is present in said mixture.

14. (Previously presented) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture thereof, optionally containing water.

15. (Canceled)

16. (Previously presented) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Previously presented) A process according to claim 16, wherein the stirring device is a high shear mixer.

18. (Previously presented) A process according to claim 10, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (Currently amended) A process according to claim [[18]] 10, wherein the agglomerates have has an average particle size between about 1 μm and 1500 μm .

20. (Currently amended) A process according to claim 10, wherein the process comprises dissolving the ~~alkali metal clavulanate salt~~ potassium clavulanate in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21-26. (Canceled)

27. (Currently amended) A process according to claim 19, wherein the agglomerates have has an average particle size about 100 μm .

28. (Currently amended) A process according to claim 19, wherein the agglomerates have has an average particle size about 1000 μm .

29. (Currently amended) A process according to claim 10, wherein the agglomerates have has a bulk density between about 0.20 g/mL and 0.60 g/mL.

30. (Canceled)

31. (Currently amended) A process according to claim 10, wherein the agglomerates have has a Carr index compressibility between about 10 % and 40 %, calculated as 100 times the

ratio of the difference between tapped bulk density and loose bulk density to the tapped bulk density.

32-33. (Canceled)

34. (Currently amended) A process according to claim 32 10, wherein the agglomerates further comprises amoxicillin.

35. (Currently amended) A process according to claim 10, wherein the agglomerates optionally contains one or more excipients.

36. (Previously presented) A process according to claim 35, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.

37. (Currently amended) An agglomerate of potassium clavulanate crystals, wherein said agglomerate has a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form and is precipitated from a solution obtained from contacting a potassium clavulanate crystal in a solvent or mixture of solvents with an anti-solvent under stirring, randomly ordered crystals of an alkali metal clavulanate salt having a Carr index compressibility of between about 10% and 40%, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

38. (Canceled)

39. (Previously presented) The agglomerate of claim 37, further comprising amoxillin.

40. (Previously presented) The agglomerate of claim 37, further comprising one or more excipients.

41. (Previously presented) The agglomerate of claim 40, wherein said one or more excipients is selected from the group consisting of microcrystalline cellulose and silica.

42. (Previously presented) The agglomerate of claim 37, wherein said agglomerate has an average particle size between about 1 μm and 1500 μm .

43. (Currently amended) The agglomerate of claim 42, wherein said agglomerates agglomerate has an average particle size of about 100 μm .

44. (Previously Presented) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 1000 μm .

45-46. (Canceled)

47. (Previously presented) A pharmaceutical formulation comprising the agglomerate of claim 37 and one or more pharmaceutically acceptable excipients.

48. (Previously presented) The pharmaceutical formulation of claim 47, further comprising amoxicillin.

49. (Previously presented) The pharmaceutical formulation of claim 47, wherein said one or more pharmaceutically acceptable inert excipients is selected from the group consisting of microcrystalline cellulose and silica.

50. (Previously presented) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 47.

51. (Previously presented) The agglomerate of claim 37, wherein said agglomerate has a loose bulk density of between about 0.2 g/mL and 0.6 g/mL.

52-53. (Canceled)

54. (Previously presented) The process of claim 10, wherein the solvent is aqueous acetone.

Please add the following new claims:

55. (New) A process for preparing potassium clavulanate in the form of an agglomerate, comprising contacting a potassium clavulanate crystal in water or ethanol, and contacting the resulting solution with an anti-solvent under stirring to cause precipitation of an agglomerate comprising potassium clavulanate,

wherein said agglomerate has a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form, and with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

56. (New) The process of claim 55, wherein the potassium clavulanate in water further comprises acetone.

57. (New) The process of claim 55, wherein said anti-solvent comprises acetone or ethyl acetate.

58. (New) The agglomerate of claim 37, wherein the agglomerate has a compressibility between about 10 % and 40 %, calculated as 100 times the ratio of the difference between tapped bulk density and loose bulk density to the tapped bulk density.

59. (New) The agglomerate of claim 37, wherein said solvent or mixture of solvent comprises water or ethanol.

60. (New) The agglomerate of claim 37, wherein said antisolvent comprises acetone.